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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/382,186 | 08/23/99 | HANSEN | H 018733/0942 |
| | | HM22/1025 | EXAMINER |
| | | | SAUNDERS, D |
| | | | ART UNIT |
| | | | PAPER NUMBER |
| | | 1644 | |
| | | DATE MAILED: | 10/25/00 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | | | |
|-----------------|----------|----------------|--------------|
| Application No. | 382,186 | Applicant(s) | HANSEN et al |
| Examiner | SAUNDERS | Group Art Unit | 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-34 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) 1-34 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All
 - Some*
 - Noneof the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of References Cited, PTO-892
- Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Other _____

Office Action Summary

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, drawn to methods of patient treatment with bi-specific antibodies and kits therefor, classified in class 424, subclasses 133.1+.
- II. Claims 30-32, drawn to methods of producing bi-specific antibodies using one host cell, classified in class 435, subclass 69.1+.
- III. Claims 33-34, drawn to methods of producing bi-specific fusion proteins using two host cells, classified in class 435, subclass 69.1+.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions II/III provide recombinant compositions which are not required for use in the method of group I. The method of group I does not require the use of any recombinant bi-specific antibodies or fusion proteins, and the products provided by the method of group II could be used in alternative methods (e.g. *in vitro* assay methods using bi-specific antibodies).

3. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions II and III employ different host cells with different encoding regions. The method of

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group II requires the use of only one host cell, while the method of group III requires the use of two host cells. A teaching of one method would thus not teach or suggest the other.

4. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Saunders whose telephone number is (703) 308-3976.

DAS

October 25, 2000

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644